

REMARKS

I. Amendments

Reconsideration of rejections in the Application is respectfully requested. Upon entry of the foregoing amendment, claims 27-33, 35-42 and 44-51 are pending in the Application. Claim 27 is amended, claim 35 is cancelled, and new claims 49-51 are added.

Applicant respectfully requests entry of the above amendment and submits that the amendment does not introduce new matter. Support for the amendments to the claims and the new claims can be found throughout the specification (considered as a whole) and in the claims as originally filed. Claim 27 has been amended to incorporate the limitation of claim 34, which has been cancelled. Support for the additional amendment to claim 27 can be found, *inter alia*, in the specification at page 9, Example 1. Support for added claim 49 can be found, *inter alia*, in the specification at page 3, lines 22-24. Support for added claims 50 and 51 can be found, *inter alia*, in the specification at page 8, lines 21-25.

Based on the above amendment and the following remarks, Applicant respectfully requests that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

II. Claim Rejections

Claims 27-30, 33-40 and 44-48 are rejected under 35 U.S.C. § 102(b) as being anticipated by Russian Patent No. RU 2,127,129, issued to Lopatin *et al.* ("the '129 patent"). Claims 27-30, 33-42 and 44-48 are rejected under 35 U.S.C. § 102(b) as being anticipated by European Patent No. EP 0727232, issued to Brunstedt *et al.* ("the '232 patent"). Claims 27, 28, 30, 33-40 and 44-48 are rejected under 35 U.S.C. § 102(b) as being anticipated by Great Britain Patent No. GB 2114578, issued to Gashinsky *et al.* ("the '578 patent").

RU 2127129

Claims 27-30, 33-40 and 44-48 are rejected under 35 U.S.C. § 102(b) as being anticipated by the '129 patent. It was asserted that the '129 patent discloses a polyacrylamide gel having a polymer content of 1.0–8.0% and a water content of 92-99% and formed from the polymerization of acrylamide and methylene-bis-acrylamide. It was further asserted that viscosity, intended uses and elasticity module are inherent properties of the allegedly identical

polymeric hydrogel set out the '129 patent. *See* Office Action, p. 2. Applicant respectfully traverses these rejections.

First, the Application claims a prosthetic device for soft tissue augmentation consisting essentially of a polymer hydrogel comprising polyacrylamide. One of ordinary skill in the art understands "polyacrylamide" to mean a polymer comprised of repeating acrylamide (C_3H_5NO) subunits. Claim 27, from which all of the other claims depend, has been amended accordingly for further clarification.

The '129 patent, on the other hand, discloses a copolymer of acrylamide *and* acrylic acid. This is supported by the first full paragraph on page 49 of the Polymeric Material Encyclopedia (Joseph C. Salamone ed., CRC Press, Inc. 1996), which is attached as Appendix A. When the polymerization of acrylamide is done in alkaline aqueous medium, as is the case in the process disclosed in the '129 patent (*see e.g.*, Translation, page 2, paragraph 5), hydrolysis of the amide occurs, thereby providing carboxylate (or ester thereof). Figure 2 of Appendix A also shows the resulting reactions: the hydrolysis of acrylamide to acrylic acid (II), the polymerization of the acid to the amide (III), and the hydrolysis of the amide in the polymer chain to the carboxylate (IV). Therefore, the content of the carboxylate subunits ("y" in Figure 2) is quite significant.

Furthermore, one of ordinary skill in the art knows that the acrylic acid (formed upon hydrolysis of the acrylamide) readily self-polymerizes. Consequently, a significant, if not predominant, portion of the backbone in the polymer chain disclosed in the '129 patent has a long chain of acrylic acid(ester) and/or a significant number of small to medium chains of acryl acid(ester). Thus, the copolymer of acrylamide and acrylic acid disclosed in the '129 patent does not anticipate the claimed polyacrylamide.

Second, claim 27 has also been amended to claim a prosthetic device having a complex viscosity of about 2 to 100 Pas. Although it has been asserted that the polymer disclosed in the '129 patent is "identical" to the polymer of the claimed prosthetic device, and thus inherently possesses the same properties of the polymer in the '129 patent, it is initially pointed out that the two polymers are, in fact, quite distinguishable as described above.

Moreover, the polymer disclosed in the '129 patent is prepared without a final washing step. *See* Translation, page 4, second full paragraph. Therefore, the desired solid weight content obtained in the polymer disclosed in the '129 patent is determined by the concentration of reagents used in the beginning. On the contrary, the reaction product of the Application has a

much higher solid weight content because the washing step disclosed in the Application affects the solid weight content of the hydrogel, which, in turn, influences the physical properties of the hydrogel. See page 3, lines 24-30. Since the process described in the '129 patent does not have a washing step, which alters the chemical nature of the polymer from the outset of the reaction process, properties such as complex viscosity and elasticity module would not be the same as the polymer disclosed in the Application.

Because copolymer of the '129 patent does not anticipate the polyacrylamide of the Application and does not inherently anticipate the physical properties of the polymer disclosed in the Application, Applicant respectfully requests that the Examiner reconsider the rejections under 35 U.S.C. § 102(b) and that the rejections be withdrawn.

EP 0 727 232

Claims 27-30, 33-42 and 44-48 are rejected under 35 U.S.C. § 102(b) as being anticipated by the '232 patent. It was asserted that the '232 patent discloses a polyacrylamide gel having a solid content of 2-20% and a viscosity of 15,000-75,000 cps and formed from the polymerization of acrylamide and methylene-bis-acrylamide. It was also asserted that since the compositions are subjected to electron beam irradiation, gamma irradiation or autoclave, they are pyrogen free. It was further asserted that limitations such as intended uses and elasticity module are all inherent properties of the allegedly identical polymeric hydrogel set out by the '232 patent. See Office Action, p. 3. Applicant respectfully traverses these rejections.

The Application claims a prosthetic device for soft tissue augmentation that is injectable into the soft tissue whereas the '232 patent discloses a *filling material*, which, in one embodiment, may comprise polyacrylamide, for an *implantable* prosthesis. Moreover, one of ordinary skill in the art would not use the filling material disclosed in the '232 patent directly as a prosthesis. Even if one were to do so, he/she would not have a reasonable expectation of success. The shell or membrane of the implant disclosed in the '232 patent provides the necessary form for the implant; therefore, one would not expect the filling material, alone, to be sufficient. Conversely, the polymer hydrogel in the Application possesses the necessary properties to perform as a prosthetic device.

Furthermore, the polyacrylamide filling material disclosed in the '232 patent is prepared by making dry polymer particles from the hydrogel. Presumably, the polymer particles are then

re-hydrated, though there is no disclosure as to the preparation of the filling material after the polymer is dried. *See* column 10, line 11 to column 11, line 47. Since the filling material of the '232 patent is that of re-hydrated polymer particles and the '232 patent seeks to avoid agglomeration of the particles (*see* column 11, line 34), the filling material of the '232 patent is in particle form. Thus, one of ordinary skill in the art would recognize that the filling material is a combination gel, which consists of macroscopic polymer fragments or microspheres suspended in a medium, rather than a homogenous gel.

As discussed above, claim 27 has been amended to claim a prosthetic device having a complex viscosity of about 2 to 100 Pas. The filling material disclosed in the '232 patent cannot be defined in terms of *complex* viscosity (one of ordinary skill in the art would recognize that "complex viscosity" is not the same physical descriptor as "viscosity") because the product is in a different physical state, namely, a combination gel (*i.e.* a two-phase suspension).

Because the combination gel filling material for an implantable prosthesis disclosed in the '232 patent does not anticipate the injectable polymer hydrogel prosthetic device having a complex viscosity as claimed in the Application, Applicant respectfully requests that the Examiner reconsider the rejections under 35 U.S.C. § 102(b) and that the rejections be withdrawn.

GB 2114578

Claims 27, 28, 30, 33-40 and 44-48 are rejected under 35 U.S.C. § 102(b) as being anticipated by the '578 patent. It was asserted that the '578 patent discloses a polyacrylamide gel with a solid content of 3-28% and a solution content of 72-97%. It was further asserted that limitations such as viscosity, intended uses and elasticity module are all inherent properties of the polymeric hydrogel set out by the '578 patent. *See* Office Action, p. 3. Applicant respectfully traverses these rejections.

As previously stated the Application claims an injectable prosthetic device for soft tissue augmentation having a complex viscosity of about 2 to 100 Pas. However, the '578 patent discloses a dense base growth medium, artificial crystalline lenses and contact lenses, which would not have a complex viscosity in the range claimed in the Application and would not be injectable. In addition, the '578 patent states that the gel can "assume the shape and size" of the container used to carry out the polymerization reaction. *See* Translation page 3, fourth full

paragraph. A polyacrylamide gel having a complex viscosity of about 2 to 100 Pas would not be able to assume a specific shape and size. Similarly, a polyacrylamide gel having a specific shape and size would not be injectable.

Because, the '578 patent does not anticipate every limitation of the claimed invention, Applicant respectfully requests that the Examiner reconsider the rejections under 35 U.S.C. § 102(b) and that the rejections be withdrawn.

III. Claim Objections

Claims 31-32 are objected to as being dependent upon a rejected base claim. In view of the above arguments regarding claim 27, from which claims 31 and 32 depend, Applicant respectfully submits that this objection is rendered moot.

CONCLUSION

For at least these reasons, claims 27-33, 35-42 and 44-51 are in condition for allowance. Accordingly, Applicant respectfully requests that the Application be reconsidered, allowed and passed to issue. In the event any outstanding issues remain, Applicant would appreciate the courtesy of a telephone call to Applicant's undersigned representative to resolve such issues in an expeditious manner.

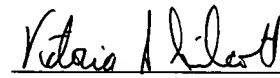
This Response is being submitted within the three-month shortened statutory period for responding. Therefore, it is believed that no fees are due. However, in the event that the USPTO determines that any fees, including extension of time fees, are required, the Commissioner is hereby authorized to charge such fees to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

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